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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

LISA GARCIA, INDIVIDUALLY AND AS
GUARDIAN AD LITEM OF E.R., MINOR

Plaintiff(s),

v.

WALMART Inc.,

Defendant.

Civil Action No.:

COMPLAINT & JURY DEMAND

DEMAND FOR JURY TRIAL

PLAINTIFF'S ORIGINAL COMPLAINT AND JURY DEMAND

Plaintiff Lisa Garcia individually and as representative of E.R., a minor, pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and through their undersigned counsel, bring this Complaint for damages against Defendant Walmart Inc., (hereinafter, "Defendant") and in support, state the following:

1. This is an action brought on behalf of Plaintiffs, Lisa Garcia (hereinafter, "Plaintiff Mother"), the natural and general guardian and mother of E.R. (hereinafter, "Plaintiff Child"), a minor, arising out of the failure of Defendant to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen (hereinafter "APAP"). As a result, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

2. Defendant entirely failed their duty to adequately warn of the hazards of prenatal exposure to APAP, which was a direct and proximate cause of Plaintiffs' injuries and associated

1 damages.

2 **STATEMENT OF PARTIES**

3 3. At all material times Plaintiffs have been citizens and residents of Orange
4 County, California.

5 4. Walmart is incorporated in Delaware, with its principal place of business in
6 Bentonville, Arkansas.

7 5. Walmart Inc., is involved in the research, development, testing, manufacture,
8 labeling, production, marketing, promotion, and/or sale of APAP through its over-the-counter
9 store brand, Acetaminophen (hereinafter, the “APAP Products”).

10 6. Walmart Inc., is individually, and jointly and severally liable to Plaintiffs for
11 damages they suffered, arising from Defendant’ design, manufacture, marketing, labeling,
12 distribution, sale, and placement of the defective APAP Products into the market, effectuated
13 directly and indirectly through its agents, servants, employees, and/or owners, all acting within
14 the course and scope of its agencies, services, employments, and/or ownership.

15 7. Walmart Inc., is vicariously liable for the acts and/or omissions of its employees
16 and/or agents, who were at all material times acting on behalf of Walmart Inc., and within the
17 scope of its employment or agency.

18 **JURISDICTION and VENUE**

19 8. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on
20 complete diversity of citizenship between Plaintiffs and Defendant. *See supra* ¶¶ 3–4.

21 9. The amount in controversy exceeds \$75,000.

22 10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or
23 omissions giving rise to Plaintiffs’ claims occurred in this judicial district.

24 11. Defendant has conducted and continue to conduct substantial business in the
25 State of California and in this District, distribute the APAP Products in this District, receive
26 substantial compensation and profits from sales of the APAP Products in this District, and have
27 made material omissions and misrepresentations and breaches of warranties in this District and
28 caused injuries in this District to Plaintiffs, among others, so as to subject Defendant to in

personam jurisdiction in this District. It was foreseeable at all times that Defendant could be haled into court in the State of California for its conduct that caused injuries to citizens of California, like Plaintiffs in this action. An exercise of in personam jurisdiction by this Court over Defendant comports fully with due process and does not offend traditional notions of fair play and substantial justice.

12. Defendant are registered to transact business in California.

FACTS COMMON TO ALL COUNTS

APAP Is Marketed as the Safe Pain Reliever for Pregnant Women, but APAP Can Cause ASD/ADHD in Children

13. APAP is widely used by pregnant women to relieve pain or discomfort during the term of their pregnancy.

14. APAP was initially discovered in the late 1800's.

15. APAP was introduced to the US market in 1955 as the first aspirin-free pain reliever. APAP was originally marketed and sold as a product to reduce fever in children, packaged like a red fire truck with the slogan, "for little hotheads."

16. Billions of units of APAP are sold annually in North America alone.

17. APAP has long been marketed as the safest, and the *only* appropriate, over-the-counter pain relief drug on the market for pregnant women.

18. Forty to 65% of pregnant women in the United States use APAP during pregnancy.

19. Based upon information and belief, a majority of women who use APAP during pregnancy do so electively for the treatment of headaches, muscle pain, back pain, and discomfort.

20. These pregnant women electively choose to take APAP because Defendant have marketed APAP as a safe pain reliever for pregnant women.

21. However, scientific and epidemiological research shows that prenatal exposure to APAP alters fetal development significantly increasing the risks of neurodevelopmental disorders, including but not limited to, autism spectrum disorder ("ASD") and attention-

1 deficit/hyperactivity disorder (“ADHD”).

2 22. Undisturbed development of the human brain in utero is vital to the health and
3 wellness of a child’s development. The human brain is vulnerable and extremely sensitive in
4 utero. During this sensitive time-period in utero, certain chemicals have been found to cause
5 permanent brain injury at low exposure levels.

6 23. Once ingested by the mother, APAP is known to readily cross the placenta and
7 blood-brain barrier.

8 24. ASD is a serious neurological and developmental disorder that affects how
9 people interact with others, communicate, learn, and behave.

10 25. There are three functional levels of ASD, with Level 1 requiring support with
11 activities of daily living, Level 2 requiring substantial support with activities of daily living, and
12 Level 3 requiring very substantial support with activities of daily living.

13 26. Treatments for ASD include behavioral management therapy, cognitive behavior
14 therapy, joint attention therapies, medications, occupational therapy, physical therapy, social
15 skill training, and speech-language therapy. Treatment for ASD lasts a lifetime, as there is no
16 cure.

17 27. ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty,
18 hyperactivity, and impulsiveness.

19 28. ADHD begins in childhood and persists through adulthood. ADHD contributes
20 to low self-esteem, troubled relationships, and difficulty with school, work, and familial
21 relationships.

22 29. Treatments for ADHD, include, but are not limited to, chronic medication usage
23 and various therapies. Treatment for ADHD lasts a lifetime, as there is no cure.

24 30. In or around 2018, the Center for Disease Control and Prevention (“CDC”)
25 found that 1 in 44 (2.3%) 8-year-old children have been diagnosed with ASD.

26 31. This represents an increase from a prior CDC finding that 1 in 68 U.S. children
27 born in 2002 have ASD, which already represented a more than a 100% increase compared with
28 children born a decade prior.

1 32. As of 2019, 8.8% of children had been diagnosed with ADHD, or roughly
2 325,000 children per year.

3 33. Parental awareness and changes in diagnoses do not fully account for the rapid
4 rise in these diagnoses.

5 34. Rather, neurotoxic exposures, such as prenatal APAP exposure, partly explain a
6 trending increase in diagnoses.

7 35. For decades, beginning in 1987, the scientific community has published studies
8 showing that prenatal ingestion of APAP can cause ASD and ADHD.

9 36. A 2019 meta-analysis of studies from 1987 to 2016, with relative risks ranging
10 from 1.16 to 1.34, found statistically significant nineteen percent (19%) increased risk of ASD
11 in children whose mothers took APAP during pregnancy.

12 37. Since 2013, there have been six European birth cohort studies, examining over
13 70,000 mother-child pairs, showing the association between prenatal use of APAP and ASD and
14 ADHD, confirming the results of studies dating back to 1987.

15 38. The overall body of scientific evidence has shown for decades that prenatal use
16 of APAP can cause ASD and ADHD in the child.

17 39. During all relevant times herein, Defendant was engaged in the business of
18 manufacturing and selling the APAP Products in the United States, and the weight of the
19 scientific evidence available showed prenatal exposure to APAP significantly increases the risk
20 of neurodevelopmental disorders in children exposed to APAP prenatally, including but not
21 limited to ASD and ADHD.

22 40. At the time Plaintiff Mother was pregnant with Plaintiff Child the scientific
23 evidence regarding the risks of in utero exposure of APAP was available to Defendant, and
24 Defendant knew or should have known that prenatal use of APAP can cause ASD or ADHD.

25 41. Moreover, despite scientific evidence that prenatal use of APAP can cause ASD
26 or ADHD, Defendant continued and continue, to market APAP Products as safe pain relievers
27 for pregnant women, making mothers believe they are choosing a safe drug for even minor
28 aches, pains, and headaches.

Plaintiff Mother Took APAP Products while Pregnant,
and It Caused ASD in Plaintiff Child

42. Plaintiff Mother used APAP Products while she was pregnant with Plaintiff Child.

43. Over the course of her pregnancy with Plaintiff Child, and during each trimester, Plaintiff Mother took the APAP Products three to four times a week.

44. Plaintiff Mother believed it was safe for her to take APAP Products during her pregnancy.

45. Indeed, Plaintiff Mother was instructed by her health care provider(s) to not take ibuprofen or aspirin while pregnant but was informed she could take APAP freely without risk to Plaintiff Child.

46. There is no warning on the APAP Products' labels specifically addressing the risks of ASD if a mother ingests APAP while pregnant.

47. Had Plaintiff Mother known of the risk of ASD in her child from taking APAP while pregnant, she would not have taken the APAP Products.

48. Plaintiff Child was born on April 7, 2009.

49. Plaintiff Mother started to have concerns about Plaintiff Child's development before he began school.

50. Plaintiff Child was diagnosed with Autism in 2012.

51. Plaintiff Child exhibits stimming behaviors in the form of repetitive, unusual body movements and/or noises such as walking on his tippy toes, flapping his arms, and twirling.

52. Plaintiff Child also is sensitive to normal household noises and covers his ears and shaking when the vacuum, blender, or blow dryer are run.

53. Plaintiff Child receives special services in the form of an individualized education program from his school for ASD.

54. Plaintiff Child requires an immense amount of assistance to complete the normal tasks of his daily life.

55. Plaintiff Child's ASD puts an incredible strain on Plaintiff Mother and their family.

56. Plaintiff's Mother fears for Plaintiff Child and experiences substantial stress and anxiety due to the challenges associated with Plaintiff Child's ASD.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

57. Due to Defendant's acts of fraudulent concealment, Defendant are estopped from relying on any statutes of limitations or repose. Such acts include Defendant's intentional concealment from Plaintiff Mother and the general public that APAP is defective when there is prenatal exposure, while continuing to market the APAP Products with the adverse effects described in this Complaint.

58. Given Defendant's affirmative actions of concealment by failing to disclose information about the defects known to it but not the public—information over which Defendant had exclusive control—and because Plaintiff Mother could not reasonably have known that the APAP Products were defective, Defendant is estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted in this Complaint.

59. Plaintiffs, in any event, commenced this action within two years of discovering or having reason to discover their causes of action.

CLAIMS FOR RELIEF

COUNT I: STRICT LIABILITY – FAILURE TO WARN

60. Plaintiffs restate, reallege, and incorporate by reference the allegations set forth in the rest of this Complaint as if fully set forth herein.

61. At the time of Plaintiffs' injuries, the APAP Products were defective and unreasonably dangerous to foreseeable consumers using the APAP Products in a foreseeable manner during pregnancy, including Plaintiff Mother, because they lacked an adequate warning.

62. At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, and promoting the APAP Products, which were defective and unreasonably dangerous to consumers, including Plaintiff

1 Mother, because they did not contain adequate warnings or instructions concerning the
2 dangerous characteristics of ingesting APAP during pregnancy. These actions were under the
3 ultimate control and supervision of Defendant. At all relevant times, Defendant registered,
4 researched, manufactured, distributed, marketed, labeled, promoted, and sold the APAP
5 Products within this District and aimed the marketing at the ultimate consumer. Defendant was
6 at all relevant times involved in the retail and promotion of the APAP Products marketed and
7 sold in this District.

8 63. Defendant had a duty to warn of the risks associated with the use of the APAP
9 products during pregnancy.

10 64. The APAP Products ingested by Plaintiff Mother during pregnancy were in the
11 same or substantially similar condition as they were when they left possession of the Defendant.

12 65. Defendant expected and intended the APAP Products to reach users such as
13 Plaintiff Mother in the condition in which the APAP Products were sold.

14 66. Plaintiff Mother did not materially alter the APAP Products prior to ingestion.

15 67. Plaintiff Mother ingested the APAP Products during pregnancy as indicated on
16 the APAP Products' labels.

17 68. Plaintiff Mother was unaware of the defects and dangers of the APAP Products
18 during pregnancy and was specifically unaware that prenatal exposure increases the risk of brain
19 and behavioral development of children in utero.

20 69. The labels on the APAP Products to consumers lack any warning specific to
21 pregnant women. The information that Defendant did provide or communicate to consumers
22 failed to contain relevant warnings, hazards, and precautions that would have enabled
23 consumers such as Plaintiff Mother to utilize the products safely and with adequate protection
24 during pregnancy, or to decide to not use or ingest the APAP Products at all.

25 70. This alleged failure to warn is not limited to the information contained on the
26 APAP Products' labeling. Defendant was able, in accord with federal law, to comply with
27 relevant state law by disclosing the known risks associated with exposure to or use of APAP
28 during pregnancy through other non-labeling mediums, including, but not limited to, promotion,

1 advertisements, public service announcements, and/or public information sources. But
2 Defendant did not disclose these known risks through any medium.

3 71. At all relevant times, Defendant had a duty to properly test, develop, design,
4 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply the
5 APAP Products; provide proper warnings for the APAP Products; and take such steps as
6 necessary to ensure the APAP Products did not cause users and consumers, and their children,
7 to suffer from unreasonable and dangerous risks. Defendant had a continuing duty to warn
8 Plaintiff Mother of dangers associated with exposure to or use of APAP during pregnancy.
9 Defendant, as a manufacturer, seller, and/or distributor of pharmaceutical medication, is held to
10 the knowledge of an expert in the field.

11 72. At the time of manufacture, Defendant could have provided the warnings or
12 instructions regarding the full and complete risks of the APAP Products during pregnancy
13 because Defendant knew or should have known of the unreasonable risks of ASD and ADHD
14 associated with prenatal exposure to and/or the use of such products.

15 73. At all relevant times, Defendant failed and deliberately refused to investigate,
16 study, test, or promote the safety of the APAP Products, or to minimize the dangers to
17 consumers of the APAP Products and to those who would foreseeably use or be harmed by the
18 APAP Products, including Plaintiffs.

19 74. Defendant failed to adequately warn consumers, like Plaintiff Mother, about the
20 significant increased risk of neurodevelopmental disorders in children exposed to APAP
21 prenatally, including but not limited to ASD and ADHD.

22 75. Defendant failed to adequately inform reasonably foreseeable consumers, like
23 Plaintiff Mother, of the proper usage of the APAP Products.

24 76. Even though Defendant knew or should have known that APAP posed a grave
25 risk of harm to Plaintiff Child, Defendant failed to exercise reasonable care to warn of the
26 dangerous risks associated with use and prenatal exposure.

27 77. Plaintiff Mother was exposed to the APAP Products during pregnancy without
28 knowledge of their dangerous characteristics.

78. At all relevant times, Plaintiff Mother used and/or was exposed to the use of the APAP Products while using them for their intended or reasonably foreseeable purposes during pregnancy, without knowledge of their dangerous characteristics.

79. Plaintiff Mother could not have reasonably discovered the defects and risks associated with the APAP Products prior to or at the time of Plaintiff consuming APAP during pregnancy. Plaintiff Mother relied upon the skill, superior knowledge, and judgment of Defendant to know about and disclose serious health risks associated with using the APAP Products.

80. If Plaintiff Mother had been properly warned of the defects, dangers, and risks associated with prenatal exposure to APAP, Plaintiff Mother would have decided to not ingest the APAP Products at all. Defendant's failure to properly warn of those defects, dangers, and risks associated with prenatal exposure to APAP was a substantial factor in causing Plaintiffs' injuries and damages.

81. Defendant is liable to Plaintiffs for injuries caused by Defendant's negligent or willful failure, as described above, to provide adequate warnings or other relevant information and data regarding the appropriate use of the APAP Products and the risks associated with the use of APAP.

82. As a direct and proximate result of Defendant placing defective APAP Products into the stream of commerce, and Plaintiff Mother's foreseeable use and ingestion of the APAP Products during pregnancy, Plaintiff Child was exposed to APAP prenatally, causing him to develop ASD.

83. As a direct and proximate result of Defendant placing defective APAP Products into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT II: NEGLIGENCE

84. Plaintiffs restate, reallege, and incorporate by reference each of the allegations set forth in the rest of this Complaint as if fully set forth herein.

1 85. Although Defendant had a duty to use reasonable care in testing, developing,
2 designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing
3 written instructions and warnings for the APAP Products, Defendant failed to do so.

4 86. Defendant, directly or indirectly, caused the APAP Products to be sold,
5 distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff Mother. At all
6 relevant times, Defendant registered, researched, manufactured, distributed, marketed,
7 promoted, and sold the APAP Products within this district and aimed at a consumer market
8 within this district.

9 87. Defendant knew, or in the exercise of reasonable care should have known, that
10 the APAP Products were defectively and unreasonably designed and/or manufactured, and/or
11 marketed, and were unreasonably dangerous and likely to injure persons that were prenatally
12 exposed to them. Defendant knew or should have known that Plaintiff Mother was unaware of
13 the dangers and defects inherent in the APAP Products when she was ingesting them during her
14 pregnancy with Plaintiff Child.

15 88. At all relevant times, Defendant had a duty to exercise reasonable care in the
16 marketing, advertisement, promotion, and sale of the APAP Products. Defendant's duty of care
17 owed to consumers and the general public included providing accurate, true, and correct
18 information concerning the risks of using APAP during pregnancy and appropriate, complete,
19 and accurate warnings concerning the potential adverse effects of APAP and, in particular, the
20 significantly increased risk of causing neurodevelopmental disorders in children through
21 prenatal exposure to APAP.

22 89. At all relevant times, Defendant knew or, in the exercise of reasonable care,
23 should have known of the hazards and dangers of APAP ingestion while pregnant and,
24 specifically, the significantly increased risk of causing neurodevelopmental disorders in
25 children through prenatal exposure to APAP.

26 90. Defendant failed to provide any kind of warning to pregnant consumers, like
27 Plaintiff Mother, about the significantly increased risk of causing neurodevelopmental disorders
28 in children through prenatal exposure to APAP.

1 91. Accordingly, at all relevant times, Defendant knew or, in the exercise of
2 reasonable care, should have known that use of the APAP Products during pregnancy could
3 cause Plaintiffs' injuries, and thus, create a dangerous and unreasonable risk of injury to the
4 users of these products, including Plaintiffs.

5 92. As such, Defendant breached their duty of reasonable care and failed to exercise
6 ordinary care in the design, research, development, manufacture, testing, marketing, labeling,
7 supply, promotion, advertisement, packaging, sale, and distribution of the APAP Products, in
8 that Defendant manufactured and produced defective APAP Products, which carry the
9 significantly increased risk of causing neurodevelopmental disorders in children through
10 prenatal exposure to APAP; knew or had reason to know of the defects inherent in the APAP
11 Products; knew or had reason to know that a user's or consumer's use of the APAP Products
12 during pregnancy created a significant risk of harm and unreasonably dangerous side effects;
13 and failed to prevent or adequately warn of these risks and injuries.

14 93. Defendant had a duty to disclose the truth about the risks associated with
15 exposure to or use of APAP during pregnancy in its promotional efforts outside of the context
16 of labeling. Defendant were negligent in its promotion of APAP outside of the labeling context
17 by failing to disclose material risk information as part of its promotion and marketing of the
18 APAP Products, including through the internet, television, and print advertisements.

19 94. Despite Defendant's ability and means to investigate, study, and test the APAP
20 Products and to provide adequate warnings regarding use during pregnancy, Defendant failed to
21 do so. Indeed, Defendant wrongfully concealed information and further made false and/or
22 misleading statements concerning the safety and use of APAP.

23 95. Defendant's negligence included:

- 24 a. Manufacturing, producing, promoting, formulating, creating, developing,
25 designing, selling, and/or distributing the APAP Products while negligently
26 and/or intentionally concealing and failing to disclose the results of trials,
27 tests, and studies of APAP and the significantly increased risk of causing
28 neurodevelopmental disorders in children through prenatal exposure to

1 APAP, and, consequently, the risk of serious harm associated with human
2 use of APAP during pregnancy; and

3 b. Failing to undertake sufficient studies and conduct necessary tests to
4 determine whether or not the APAP Products were safe for its intended
5 consumer use and unborn children; and

6 c. Failing to provide adequate instructions, guidelines, and safety precautions to
7 those persons Defendant could reasonably foresee would use the APAP
8 Products during pregnancy; and

9 d. Failing to disclose to Plaintiff Mother, users, consumers, and the general
10 public that use of APAP during pregnancy presents severe risks of
11 neurodevelopmental disorders in children exposed to APAP prenatally; and

12 e. Failing to warn Plaintiff Mother, users, consumers, and the general public
13 that the APAP Products' risk of harm was unreasonable and that there were
14 safer and effective alternative medications or treatments available to Plaintiff
15 Mother and other users and/or consumers; and

16 f. Representing that the APAP Products were safe for their intended purposes
17 for pregnant women when, in fact, Defendant knew or should have known
18 the APAP Products were not safe for their intended purposes; and

19 g. Declining to make or propose any changes to the APAP Products' labeling or
20 other promotional materials that would alert users, consumers, and the
21 general public of the risks of APAP, including to pregnant women; and

22 h. Advertising, marketing, and recommending the use of the APAP Products
23 during pregnancy, while concealing and failing to disclose or warn of the
24 dangers known by Defendant to be caused by the use of or exposure to
25 APAP; and

26 i. Continuing to disseminate information to its consumers and the general
27 public, which indicates or implies that the APAP Products are not unsafe for
28 pregnant consumer use; and

1 j. Continuing the manufacture and sale of the APAP Products with the
2 knowledge that the APAP Products were unreasonably unsafe and dangerous.

3 96. Defendant knew and/or should have known that it was foreseeable that children
4 such as Plaintiff Child would suffer injuries as a result of Defendant's failure to exercise
5 ordinary care in the manufacturing, marketing, labeling, distribution, and sale of the APAP
6 Products to pregnant consumers, like Plaintiff Mother.

7 97. Plaintiff Mother did not know the nature and extent of the injuries that could
8 result in her child from the intended use of and/or exposure to APAP prenatally.

9 98. Defendant's negligence was a proximate cause of Plaintiffs' injuries, i.e., absent
10 Defendant's negligence, Plaintiff Child would not have developed ASD. That negligence was a
11 substantial factor in causing Plaintiffs' injuries and damages.

12 99. Defendant's conduct, as described above, was reckless. Defendant regularly
13 risked exposing Plaintiff Mother to the APAP Products while pregnant with Plaintiff Child, with
14 full knowledge of the dangers of the APAP Products and that it could cause ASD in Plaintiff
15 Child. Defendant made conscious decisions not to redesign, re-label, warn, or inform the
16 unsuspecting public, including Plaintiff Mother. Defendant's reckless conduct therefore
17 warrants an award of punitive damages.

18 100. As a direct and proximate result of Defendant placing the defective APAP
19 Products into the stream of commerce, Plaintiffs have suffered permanent injuries, significant
20 pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality
21 of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

22
23 **COUNT III: BREACH OF EXPRESS WARRANTY**

24 101. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
25 set forth in the rest of this Complaint as if fully set forth herein.

26 102. At all material times, Defendant manufactured, marketed, sold, distributed, and
27 otherwise placed into the stream of commerce the APAP Products. These actions were under
28 the ultimate control and supervision of Defendant.

103. In advertising, marketing, and promoting the APAP Products to consumers, like Plaintiff Mother, Defendant expressly warranted that the APAP Products were safe for use and reasonably fit for their intended purposes, including use by pregnant mothers. In advertising, marketing, and otherwise promoting the APAP Products, Defendant intended for pregnant consumers to rely upon its representations regarding safety and fitness, in an effort to induce them to purchase and consume the APAP Products during pregnancy to relieve pain.

104. Defendant expressly warranted to Plaintiff Mother and pregnant consumers that the APAP Products were safe for ingestion during pregnancy.

105. Defendant had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of the APAP Products, including a duty to:

- a. ensure that the APAP Products during pregnancy did not cause users and their unborn children unreasonably dangerous side effects; and
- b. warn of dangerous and potentially incurable side effects; and
- c. disclose adverse material facts, such as the true risks associated with the use of and exposure to APAP during pregnancy, when making representations to users, consumers, and the general public, including Plaintiff Mother.

106. Defendant had the ability to properly disclose the risks associated with APAP usage during pregnancy through multiple channels, not just labeling.

107. At all relevant times, Defendant expressly represented and warranted to the purchasers of the APAP Products, by and through statements made by Defendant in labels, publications, brochures, and other written materials intended for consumers and the general public, that the APAP Products were safe to human health and the environment, effective, fit, and proper for their intended use during pregnancy. Defendant advertised, labeled, marketed, and promoted the APAP Products, representing the quality to consumers and the public in such a way as to induce their purchases or use during pregnancy, thereby making an express warranty that the APAP Products would conform to the representations.

108. The representations about the APAP Products, as set forth herein, contained, or

1 constituted affirmations of fact or promises made by the seller to the buyer, which related to the
2 goods and became part of the basis of the bargain, creating an express warranty that the goods
3 would conform to the representations.

4 109. Defendant breached express representations and warranties made to Plaintiff
5 Mother, with respect to the APAP Products, including the following:

- 6 a. Defendant represented through their labeling, advertising, and marketing
7 materials that the APAP Products were safe for use during pregnancy, and
8 intentionally withheld and concealed information about the risks of serious
9 injury associated with use of APAP and by expressly limiting the risks
10 associated with use during pregnancy within its warnings and labels; and
11 b. Defendant represented that the APAP Products were safe for use and
12 intentionally concealed information that demonstrated that APAP carries the
13 significantly increased risk of causing neurodevelopmental disorders in
14 children through prenatal exposure to APAP, and that the APAP Products,
15 therefore, were not safer than alternatives available on the market.

16 110. Plaintiff Mother detrimentally relied on the express warranties and
17 representations of Defendant concerning the safety and/or risk profile of APAP during
18 pregnancy in deciding to purchase the APAP Products. Plaintiff Mother reasonably relied upon
19 Defendant to disclose known defects, risks, dangers, and side effects of APAP. Plaintiff Mother
20 would not have purchased or used the APAP Products during pregnancy had Defendant
21 properly disclosed the risks associated with the APAP Products, either through advertising,
22 labeling, or any other form of disclosure. Defendant's breach of the express warranties and
23 representations concerning the safety and/or risk profile of APAP during pregnancy was a
24 substantial factor in causing Plaintiffs' injuries and damages.

25 111. Plaintiff Mother had no knowledge of the falsity or incompleteness of
26 Defendant's statements and representations concerning the APAP Products and could not have
27 taken reasonable steps to notify Defendant of those matters or to seek repair or other remedies.

28 112. Plaintiff Mother used and/or was exposed to APAP during pregnancy as

1 researched, developed, designed, tested, manufactured, inspected, labeled, distributed,
2 packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by
3 Defendant.

4 113. Had the warnings, labels, advertisements, or promotional material for the APAP
5 Products accurately and adequately set forth the true risks associated with the use of such
6 Products during pregnancy, including Plaintiffs' injuries, rather than expressly excluding such
7 information, and warranting that the APAP Products were safe for their intended use, Plaintiffs
8 could have avoided the injuries complained of herein.

9 114. As a direct and proximate result of Defendant's breach of express warranty,
10 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress,
11 lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all
12 damages to which they may be legally entitled.

13 **COUNT IV: BREACH OF IMPLIED WARRANTY**

14 115. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
15 set forth in the rest of this Complaint as if fully set forth herein.

16 116. At all material times, Defendant manufactured, marketed, sold, distributed, and
17 otherwise placed the APAP Products into the stream of commerce.

18 117. At all material times, Defendant intended for the APAP Products to be consumed
19 and ingested by pregnant women, like Plaintiff Mother; and Defendant impliedly warranted that
20 the APAP Products and their component parts were of merchantable quality, safe, fit for such
21 use, and adequately tested.

22 118. Defendant was aware that consumers, including Plaintiff Mother, would
23 consume and ingest the APAP Products as directed by the Products' labels and promotional
24 materials. Therefore, Plaintiff Mother was a foreseeable user of the APAP Products.

25 119. But Defendant failed to disclose that APAP has dangerous propensities when
26 used as intended during pregnancy and that use of the APAP Products carries an increased risk
27 of developing severe injuries, including Plaintiff Child's injuries.

28 120. The APAP Products were expected to reach, and did in fact reach consumers,

1 including Plaintiff Mother, without substantial change in the condition in which they were
2 manufactured and sold by Defendant.

3 121. Plaintiff Mother was an intended beneficiary of the implied warranties made by
4 Defendant to purchasers of the APAP Products, including Plaintiff Mother.

5 122. In reliance upon Defendant's implied warranties, Plaintiff Mother purchased and
6 used the APAP Products as indicated, and in the foreseeable manner normally intended,
7 recommended, promoted, and marketed by Defendant. The failure of the APAP Products to be
8 of merchantable quality, to be safe or fit for their intended use, or to be adequately tested was a
9 substantial factor in causing Plaintiffs' injuries and damages.

10 123. Defendant breached their implied warranties to Plaintiffs in that the APAP
11 Products were not of merchantable quality, nor were they safe or fit for their intended use or
12 adequately tested.

13 124. The harm caused by the APAP Products far outweighed their benefit, rendering
14 the APAP Products more dangerous than an ordinary consumer or user would expect and more
15 dangerous than alternative products.

16 125. As a direct and proximate result of Defendant's breach of implied warranties,
17 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress,
18 lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all
19 damages to which they may be legally entitled.

20 **COUNT V: VIOLATION OF CONSUMER PROTECTION LAWS**

21 126. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
22 set forth in the rest of this Complaint as if fully set forth herein.

23 127. Plaintiff Mother purchased and used the APAP Products for primarily personal
24 use and pain relief during pregnancy, thereby suffering ascertainable losses as a result of
25 Defendant's actions in violation of the consumer protection laws.

26 128. Had Defendant not engaged in the deceptive conduct described in this
27 Complaint, Plaintiff would not have purchased and/or paid for the APAP Products, and
28 Plaintiffs would not have incurred related injury medical costs.

1 129. Defendant engaged in wrongful conduct and unlawful while at the same time
2 obtaining under false pretenses moneys from Plaintiff for the APAP Products. Those moneys
3 would not have been paid had Defendant not engaged in unfair and deceptive conduct. Plaintiffs
4 actually relied upon Defendant's misrepresentations and deception concerning the APAP
5 Products.

6 130. Defendant engaged in the following unfair methods of competition or deceptive
7 acts or practices, which are proscribed by law:

- 8 A. representing that goods or services have characteristics,
9 ingredients, uses, benefits, or qualities they do not have; and
- 10 B. advertising goods or services with the intent not to sell them as
11 advertised; and
- 12 C. engaging in fraudulent or deceptive conduct creating a likelihood
13 of confusion or misunderstanding.

14 131. Plaintiffs were injured by the cumulative nature of Defendant's conduct. The
15 cumulative effect, directed at patients, physicians, and consumers, was to create demand for and
16 sell the APAP Products. Each aspect of Defendant's conduct combined to artificially create
17 sales of the APAP Products, including to Plaintiff Mother who did, in fact, purchase the APAP
18 Products.

19 132. Defendant had a statutory duty to refrain from unfair or deceptive acts or trade
20 practices in the design, labeling, development, manufacture, promotion, and sale of the APAP
21 Products.

22 133. Defendant's deceptive, unconscionable, or fraudulent representations and
23 material omissions to consumers, including Plaintiff Mother, constitute unfair and deceptive
24 acts and trade practices in violation of the federal and state consumer protection statutes listed
25 below.

26 134. Defendant's actions, as complained of in this Complaint, constitute unfair
27 competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in
28 violation of the federal and state consumer protection statutes listed below.

135. Defendant has engaged in unfair competition, or unfair or deceptive acts or trade practices, or has made false representations under the following statutes:

- 15 U.S.C. §§ 2301–12 (1982);
- Cal. Bus. & Prof. Code § 17200, et seq.;
- Cal. Civ. Code § 1750 et seq.

136. To protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising, Defendant, as the supplier, manufacturer, advertiser, and seller, is subject to liability under the above legislation enacted against unfair, deceptive, fraudulent, and unconscionable consumer sales practices. The California Unfair Competition Law (“UCL”) prohibits “any unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue, or misleading advertising and any act prohibited by” Section 17500 of the California Business and Professions Code. Section 17500, in turn, prohibits any untrue or misleading statements made in connection with the sale of goods. The Consumers Legal Remedies Act (“CLRA”) defines as statutorily unlawful certain unfair methods of competition and unfair or deceptive practices. Cal. Civ. Code § 1750 et seq.

137. By knowingly and falsely representing that the APAP Products were fit to be used for the purposes for which they were intended—when in fact they were defective and dangerous when used during pregnancy—and by other acts alleged, Defendant violated the above statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising.

138. Defendant’s actions and omissions are uncured or incurable, deceptive acts under the above legislation.

139. Defendant had actual knowledge of the defective and dangerous conditions of the APAP products but failed to take any action to cure such defective and dangerous conditions.

140. Plaintiff Mother relied upon Defendant’s misrepresentations and omissions in determining which APAP Products (if any) to ingest.

141. Defendant’s deceptive, unconscionable, or fraudulent representations and

1 material omissions to consumers constituted unfair and deceptive acts and practices.

2 142. By reason of the unlawful acts in which Defendant engaged, and as a direct and
3 proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

4 143. As a direct and proximate result of Defendant's violations of the above-listed
5 legislation, Plaintiffs have sustained economic losses and other damages and are entitled to
6 statutory and compensatory damages, including restitution, in an amount to be proven at trial
7 and civil penalties as permitted by law.

8 **COUNT VI: NEGLIGENT MISREPRESENTATION**

9 144. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
10 set forth in the rest of this Complaint as if fully set forth herein.

11 145. Defendant had a duty to accurately and truthfully represent to consumers,
12 including to Plaintiff Mother and to the public, that the APAP Products had not been adequately
13 tested and found to be a safe and effective treatment for pregnant women. Defendant breached
14 that duty as its representations of the safety of the APAP Products were false. Defendant
15 intended for consumers like Plaintiff Mother to rely upon that representation, Plaintiff Mother
16 did justifiably rely on Defendant's misrepresentations concerning the APAP Products' high risk
17 of unreasonable and dangerous adverse side effects when ingested or used during pregnancy.

18 146. Defendant failed to exercise ordinary care in the representations concerning the
19 APAP Products while Defendant were involved in the manufacture, sale, testing, quality
20 assurance, quality control, and distribution in interstate commerce, because Defendant
21 negligently misrepresented the APAP Products' high risk of unreasonable and dangerous
22 adverse side effects when ingested or used during pregnancy.

23 147. Defendant also breached their duty in representing to Plaintiff Mother that the
24 APAP Products had no serious side effects when ingested during pregnancy. Defendant
25 intended for consumers like Plaintiff Mother to rely upon that representation, and Plaintiff
26 Mother did justifiably rely upon that representation.

27 148. Defendant knew or had reason to know that the APAP Products had been
28 insufficiently tested or had not been tested at all; and that they lacked adequate and accurate

1 warnings, and created a high risk, or a higher than acceptable reported and represented risk, of
2 adverse side effects. Those side effects include neurodevelopmental disorders in children, such
3 as ASD and ADHD. Thus, Defendant lacked reasonable ground for believing the
4 representations to be true and intended for consumers like Plaintiff to rely upon those
5 misrepresentations by purchasing the APAP products for use during pregnancy. Plaintiff
6 Mother justifiably relied upon those misrepresentations in purchasing and using the APAP
7 products while pregnant. Defendant's negligent misrepresentations concerning the safety
8 and/or risk profile of using APAP during pregnancy was a substantial factor in causing
9 Plaintiffs' injuries and damages.

10 149. As a direct and proximate result of Defendant's negligent misrepresentation,
11 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress,
12 lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all
13 damages to which they may be legally entitled.

14 **PUNITIVE DAMAGES**

15 150. Plaintiffs restate, reallege, and incorporate by reference each of the allegations
16 set forth in the rest of this Complaint as if fully set forth herein.

17 151. Defendant has acted with malice through despicable conduct that exhibits a
18 willful and conscious disregard for the rights and safety of others, including Plaintiffs, and has
19 acted with oppression in subjecting Plaintiffs to cruel and unjust hardship in conscious disregard
20 of their rights. Further, Defendant has intentionally misrepresented or concealed material facts
21 known to it with the intention of causing injury or otherwise depriving Plaintiffs of their
22 property or legal rights.

23 152. Defendant failed to adequately test and study the APAP Products to determine
24 and ensure that the APAP Products were safe and effective for use during pregnancy before
25 releasing them for sale for human consumption.

26 153. Further, Defendant continued to manufacture and sell the APAP Products and
27 marketed them for use during pregnancy, even after obtaining knowledge and information that
28 the APAP Products were defective and unreasonably unsafe because they, among other things,

1 did not include adequate warnings.

2 154. Defendant was aware of the probable consequences of the dangerous and
3 defective product, including the risk of neurodevelopmental disorders in children, such as ASD
4 and ADHD, when they suffered prenatal exposure.

5 155. At all material times, Defendant knew or should have known that the APAP
6 Products were inherently dangerous with respect to the following: the risk of
7 neurodevelopmental disorders in children, such as ASD and ADHD, when they suffered
8 prenatal exposure; pain and suffering; loss of life's enjoyment; and unsuccessful treatments to
9 cure the conditions proximately related to the use of the APAP Products, as well as the other
10 permanent and lasting severe personal injuries.

11 156. Defendant knowingly withheld material information from consumers and the
12 public, including Plaintiff Mother, concerning the safety and efficacy of the APAP Products
13 during pregnancy, which deprived Plaintiff Mother of vitally necessary information with which
14 to make a fully informed decision about whether to use the APAP Products while pregnant.

15 157. At all material times, Defendant also knew and recklessly and/or intentionally
16 disregarded the fact that the APAP Products, when used during pregnancy, can cause
17 debilitating and life-altering side effects with greater frequency than safer alternative methods,
18 products, and/or treatments. But Defendant recklessly failed to advise the medical community
19 and the general public, including Plaintiff Mother, of that fact.

20 158. At all material times, Defendant intentionally misstated and misrepresented data;
21 and Defendant continue to misrepresent data so as to minimize the perceived risk of injuries and
22 the rate of complications caused by or associated with the APAP Products.

23 159. Notwithstanding the foregoing and the growing body of knowledge and
24 information regarding the true and defective nature of the APAP Products, with their increased
25 risk of side effects and serious complications, Defendant continues to aggressively market the
26 APAP Products to consumers, including the pregnant community at large, without disclosing
27 the true risk of the complications and side effects.
28

and

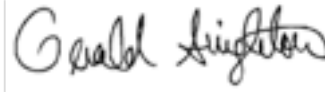
- ii. Restitution and disgorgement of Defendant's profits; and
- iii. Punitive or enhanced compensatory damages; and
- iv. Reasonable attorneys' fees as provided by law; and
- v. Past and future costs of all proceedings; and
- vi. All ascertainable economic damages; and
- vii. Prejudgment interest on all damages as allowed by law; and
- viii. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demands a trial by jury on all issues so triable.

Dated: August 26, 2022

Respectfully submitted,



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